Attorney Docket No Q67462

Amendment Under 37 C.F.R. § 1.111

Appln. No. 10/018,783

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the

application:

LISTING OF CLAIMS:

1-22. (Canceled)

23. (Currently amended) A kit comprising a balloon catheter comprising a balloon at

or near its distal end, and a stent mounted on the balloon, wherein the exterior surface of the

balloon and stent are provided with a coherent coating comprising a film-forming polymer and

the stent is formed from a metal tube.

24. (Previously presented) A kit according to claim 23 in which the coating is

continuous around the circumference of the exterior surface of the balloon and stent over at least

a portion of the axial extent of the stent.

25. (Previously presented) A kit according to claim 24 in which the coating extends

along the entire axial length of the stent.

26. (Previously presented) A kit according to claim 25 in which the coating extends

beyond both ends of the stent.

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- 27. (Previously presented) A kit according to claim 23 in which the polymer of the coating is cross-linked.
- 28. (Previously presented) A kit according to claim 23 in which the polymer has pendent zwitterionic groups.
- 29. (Previously presented) A kit according to claim 28 in which the polymer is formed from ethylenically unsaturated monomers including a zwitterionic monomer of the general formula I:

wherein

B is a straight or branched alkanediyl, alkyleneoxaalkylene or alkylene oligo-oxaalkylene chain optionally containing one or more fluorine atoms up to and including perfluorinated chains or, if X or Y contains a terminal carbon atom bonded to B, a valence bond;

X is a zwitterionic group; and

Y is an ethylenically unsaturated polymerisable group selected from the group consisting of

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$$\label{eq:ch2} \begin{split} & \text{CH}_2\text{=C}(R)\text{-CH}_2\text{-O-, CH}_2\text{=C}(R)\text{-CH}_2\text{OC}(O)\text{-, CH}_2\text{=C}(R)\text{OC}(O)\text{-, CH}_2\text{=C}(R)\text{-O-,} \\ & \text{CH}_2\text{=C}(R)\text{CH}_2\text{OC}(O)\text{N}(R^1)\text{-, R}^2\text{OOCCR}\text{=CRC}(O)\text{-O-, RCH}\text{=CHC}(O)\text{O-,} \\ & \text{RCH}\text{=C}(\text{COOR}^2)\text{CH}_2\text{-C}(O)\text{-O-,} \end{split}$$

wherein:

R is hydrogen or a C_1 - C_4 alkyl group;

R¹ is hydrogen or a C₁-C₄ alkyl group or R¹ is -B-X where B and X are as defined above; and

 R^2 is hydrogen or a C_{1-4} alkyl group;

A is -O- or $-NR^1-$;

K is selected from the group consisting of $-(CH_2)_DOC(O)$, $-(CH_2)_DC(O)O$,

 $-(CH_2)_DOC(O)O-$, $-(CH_2)_DNR^3-$, $-(CH_2)_DNR^3C(O)-$,

 $-(CH_2)_pC(O)NR^3-$, $-(CH_2)_pNR^3C(O)O-$, $-(CH_2)_pOC(O)NR^3-$,

 $-(CH_2)_pNR^3C(O)NR^3$ - (in which the groups R^3 are the same or different), $-(CH_2)_pO$ -,

(CH₂)_pSO₃ -, and, optionally in combination with B, a valence bond

p is from 1 to 12; and

 R^3 is hydrogen or a C_1 - C_4 alkyl group.

30. (Previously presented) A kit according to claim 29 in which X is a group having the general formula III

in which the moieties A^2 and A^3 , which are the same or different, are selected from the group consisting of -0-, -S-, -NH- and a valence bond, and W^+ is a group comprising a cationic group selected from the group consisting of ammonium, phosphonium and sulphonium cationic groups and a group linking the anionic and cationic moieties which is a C_{1-12} -alkanediyl group.

- 31. (Previously presented) A kit according to claim 30 in which A² and A³ are each -O-.
- 32. (Previously presented) A kit according to claim 30 in which W⁺ is a group of formula

 $-W^{1}-N^{+}R^{9}_{3}$, $-W^{1}-P^{+}R^{10}_{3}$, $-W^{1}-S^{+}R^{10}_{2}$ or $-W^{1}-Het^{+}$ in which:

W¹ is selected from the group consisting of alkanediyl of 1-6 carbon atoms optionally containing one or more ethylenically unsaturated double or triple bonds,

disubstituted-aryl (arylene), alkylene arylene, arylene alkylene, alkylene aryl alkylene, cycloalkanediyl, alkylene cycloalkyl, cycloalkyl alkylene and alkylene cycloalkyl alkylene, which group W¹ optionally contains one or more fluorine substituents and/or one or more functional groups; and

either the groups R⁹ are the same or different and each is selected from the group consisting of hydrogen, alkyl of 1 to 4 carbon atoms and aryl, or two of the groups R⁹ together with the nitrogen atom to which they are attached form an aliphatic heterocyclic ring containing from 5 to 7 atoms, or the three groups R⁹ together with the nitrogen atom to which they are attached form a fused ring structure containing from 5 to 7 atoms in each ring, and optionally one or more of the groups R⁹ is substituted by a hydrophilic functional group, and

the groups R^{10} are the same or different and each is R^9 or a group OR^9 , where R^9 is as defined above; or

Het is an aromatic nitrogen-, phosphorus- or sulphur-containing ring.

33. (Previously presented) A kit according to claim 29 in which X is a group having the general formula IV:

where the groups R^{11} are the same or different and each is hydrogen or $C_{1.4}$ alkyl, and m is from 1 to 4.

- 34. (Previously presented) A kit according to claim 33 in which the groups R¹¹ are the same.
- 35. (Previously presented) A kit according to claim 34 in which the groups R^{11} are all methyl.
- 36. (Previously presented) A kit according to claim 29 in which the ethylenically unsaturated monomers include a surface binding monomer having the general formula II

$$Y^1\,R^4 \hspace{1.5cm} II$$

wherein Y¹ is selected from the group consisting of

 $CH_2=C(R^5)-CH_2-O-, CH_2=C(R^5)-CH_2 OC(O)-, CH_2=C(R^5)OC(O)-, CH_2=C(R^5)-O-, CH_2=C(R^5)CH_2OC(O)N(R^6)-, R^7OOCCR^5=CR^5C(O)-O-, R^5CH=CHC(O)O-, R^5CH=C(COOR^7)CH_2-C(O)-O-,$

wherein:

R⁵ is hydrogen or a C₁-C₄ alkyl group;

R⁶ is hydrogen or a C₁,-C₄ alkyl group or R⁶ is R⁴;

R⁷ is hydrogen or a C₁₋₄ alkyl group;

A¹ is -O- or -NR⁶-; and

 K^1 is selected from the group consisting of -(CH₂)_qOC(O)-, -(CH₂)_qC(O)O-,

 $-(CH_2)_q OC(O)O-, -(CH_2)_q NR^8-, -(CH_2)_q NR^8C(O)-, -(CH_2)_q C(O)NR^8-,$

 $-(CH_2)_qNR^8C(O)O-, -(CH_2)_qOC(O)NR^8-, -(CH_2)_qNR^8C(O)NR^8- \ \, (in which the groups \ \, R^8 \ \, are the same or different), -(CH_2)_qO-, -(CH_2)_qSO_3-, and a valence bond$

q is from 1 to 12;

and R⁸ is hydrogen or a C₁-C₄ alkyl group;

and R₄ is a surface binding group, selected from hydrophobic groups, ionic groups, reactive groups capable of forming covalent bonds with surface functional groups on the surface

of the tube and crosslinkable groups capable of forming intermolecular crosslinks, optionally in conjunction with curing agents.

37. (Previously presented) A kit according to claim 27 in which the polymer is formed from ethylenically unsaturated monomers including a monomer of formula VIII

$$Y^2 R^{30} Q^1$$

VIII

wherein

Y² is selected from the group consisting of

$$H_2C = C - C - A^7 - C$$

$$\begin{split} & \text{CH}_2 = \text{C}(R^{23}) - \text{CH}_2 = \text{C}(R^{23}) - \text{CH}_2 = \text{C}(R^{23}) - \text{CH}_2 = \text{C}(R^{23}) - \text{OC}(O) -, \ \text{CH}_2 = \text{C}(R^{23}) - \text{C}(O) -, \ \text{CH}_2 = \text{C}(R^{23}) -, \ \text{CH}_2 = \text{C}(R^{23})$$

$$R^{23}HC$$
 N
 $R^{23}C$
 N
 $R^{23}C$
 N
 $R^{23}C$
 N

wherein:

R²³ is hydrogen or a C₁-C₄ alkyl group;

 R^{24} is hydrogen or a C_1 - C_4 alkyl group or R^{24} is R^{30} Q^1 ;

R²⁵ is hydrogen or a C₁₋₄ alkyl group;

 A^7 is -O- or -NR²⁴-; and

K² is selected from the group consisting of -(CH₂)_tOC(O)-, -(CH₂)_tC(O)O-,

 $-(CH_2)_tOC(O)O-, -(CH_2)_tNR^{28}-, -(CH_2)_tNR^{28}C(O)-, -(CH_2)_tC(O)NR^{28},\\$

- $(CH_2)_tNR^{28}C(O)O$ -, - $(CH_2)_tOC(O)NR^{28}$ -, - $(CH_2)_tNR^{28}C(O)NR^{28}$ - (in which the groups R^{28} are the same or different), - $(CH_2)_tO$ -, - $(CH_2)_tSO_3$ -, and a valence bond

t is from 1 to 12;

and R²⁸ is hydrogen or a C₁-C₄ alkyl group;

 R^{30} is a straight or branched C_{2-24} alkanediyl group, or a alkylenoxaalkylene or alkylene(oligo-oxaalkylene) group in which each alkylene has 2 to 12 carbon atoms, and

 Q^1 is a group $Si(OR^{26})_3$ in which the groups R^{26} are independently selected from C_{1-4} alkyl groups.

38. (Previously presented) A kit according to claim 37 in which Y^2 is

in which R^{23} is methyl, and A^7 is -O-, R^{30} is C_{2-6} alkanediyl and each R^{26} is C^{1-2} -alkyl.

- 39. (Previously presented) A kit according to claim 38 in which each R^{26} is methyl.
- 40. (Previously presented) A kit according to claim 23 which is sterile.

41. (Canceled)

- 42. (Previously presented) A kit according to claim 25 in which the stent is formed of stainless steel.
- 43. (Previously presented) A kit according to claim 29 in which the ethylenically unsaturated monomers comprise
 - a) a zwitterionic monomer of the general formula

in which

R is hydrogen or methyl;

B is C₂₋₆-alkanediyl; and

X is a group having the general formula IV:

where the groups R^{11} are the same or different and each is hydrogen or C_{1-4} alkyl, and m is from 1 to 4;

b) a surface binding monomer of the general formula

in which

R⁵ is hydrogen or methyl; and

R⁴ is selected from the group consisting of straight and branched alkyl, alkoxyalkyl and oligoalkoxyalkyl groups comprising 6 to 24 carbon atoms, unsubstituted or substituted by one or more fluorine atoms and optionally containing one or more carbon-carbon double or triple bonds; and

c) a silyl group containing monomer of the general formula

in which

R²³ is hydrogen or methyl;

R³⁰ is a C₂₋₂₄ alkanediyl group; and

each R²⁶ is methyl or ethyl.

- 44. (Withdrawn) A method for providing a kit comprising the steps:
- a) providing an assembly comprising a balloon catheter and, mounted on the balloon of the balloon catheter, a stent;
- b) coating at least a portion of the assembly with a liquid coating composition containing a film-forming polymer; and

- c) curing the coating composition to leave a coherent film of polymer on the exterior surface of the stent and balloon.
- 45. (Withdrawn) A method according to claim 44 in which in step b) the balloon and stent assembly is dipped into the liquid coating composition.
- 46. (Withdrawn) A method according to claim 45 in which the balloon catheter has a guidewire lumen passing through the balloon and the lumen is blocked during step b).
- 47. (Withdrawn) A method according to claim 44 in which curing the liquid coating composition comprises a solvent and step c) involves removal of solvent from the liquid coating composition.
- 48. (Withdrawn) A method according to claim 47 in which solvent is removed by evaporation.
- 49. (Withdrawn) A method according to claim 48 in which the solvent in the coating composition is selected from the group consisting of water, alcohol, ether, alkanes and mixtures thereof.

- 50. (Withdrawn) A method according to claim 49 in which the solvent comprises a mixture of ethanol with water or with an alkane.
- 51. (Withdrawn) A method according to claim 44 in which the film-forming polymer is cross-linkable and the curing step includes a step of cross-linking the polymer.
- 52. (Withdrawn) A method according to claim 51 in which the polymer is formed from ethylenically unsaturated monomers including a monomer of formula VIII

$$Y^2R^{30}Q^1$$

VIII

wherein

Y² is selected from the group consisting of

$$\begin{split} & \text{CH}_2 = \text{C}(R^{23}) - \text{CH}_2 - \text{O-, CH}_2 = \text{C}(R^{23}) - \text{CH}_2 \text{ OC(O)-, CH}_2 = \text{C}(R^{23}) \text{OC(O)-, CH}_2 = \text{C}(R^{23}) - \text{O-,} \\ & \text{CH}_2 = \text{C}(R^{23}) \text{CH}_2 \text{OC(O)N}(R^{24}) - \text{, R}^{25} \text{OOCCR}^{23} = \text{CR}^{23} \text{C(O)-0-, R}^{23} \text{CH} = \text{CHC(O)O-,} \\ & \text{R}^{23} \text{CH} = \text{C}(\text{COOR}^{25}) \text{CH}_2 - \text{C(O)-O-,} \end{split}$$

wherein:

R²³ is hydrogen or a C₁-C₄ alkyl group;

R²⁴ is hydrogen or a C₁-C₄ alkyl group or R²⁴ is R³⁰ Q¹;

 R^{25} is hydrogen or a C_{1-4} alkyl group;

 A^7 is -O- or -NR²⁴-; and

 K^2 is selected from the group consisting of -(CH₂)_tOC(O)-, -(CH₂)_tC(O)O-,

 $-(CH_2)_tOC(O)O_{-}$, $-(CH_2)_tNR^{28}$ -, $-(CH_2)_tNR^{28}C(O)$ -, $-(CH_2)_tC(O)NR^{28}$,

- $(CH_2)_tNR^{28}C(O)O$ -, - $(CH_2)_tOC(O)NR^{28}$ -, - $(CH_2)_tNR^{28}C(O)NR^{28}$ - (in which the groups R^{28} are the same or different), - $(CH_2)_tO$ -, - $(CH_2)_tSO_3$ -, and a valence bond

t is from 1 to 12;

and R²⁸ is hydrogen or a C₁-C₄ alkyl group;

 R^{30} is a straight or branched C_{2-24} alkanediyl group, or a alkylenoxaalkylene or alkylene(oligo-oxaalkylene) group in which each alkylene has 2 to 12 carbon atoms, and

 Q^1 is a group $Si(OR^{26})_3$ in which the groups R^{26} are independently selected from C_{1-4} alkyl groups.

- 53. (Withdrawn) A method according to claim 44 in which the film-forming polymer has pendant zwitterionic groups.
- 54. (Withdrawn) A method according to claim 53 in which the polymer is formed from ethylenically unsaturated monomers including a zwitterionic monomer of the general formula I:

wherein

B is a straight or branched alkanediyl, alkyleneoxaalkylene or alkylene oligo-oxaalkylene chain optionally containing one or more fluorine atoms up to and including perfluorinated chains or, if X or Y contains a terminal carbon atom bonded to B, a valence bond;

X is a zwitterionic group; and

Y is an ethylenically unsaturated polymerisable group selected from the group consisting of

$$H_2C = C - C - A - C$$

$$CH_2=C(R)-CH_2-O-, CH_2=C(R)-CH_2OC(O)-, CH_2=C(R)OC(O)-, CH_2=C(R)-O-, \\ CH_2=C(R)CH_2OC(O)N(R^1)-, R^2OOCCR=CRC(O)-O-, RCH=CHC(O)O-, \\ RCH=C(COOR^2)CH_2-C(O)-O-, \\ RCH=C(COOR^2)CH_2-C(O)$$

wherein:

R is hydrogen or a C₁-C₄ alkyl group;

 R^1 is hydrogen or a C_1 - C_4 alkyl group or R^1 is -B-X where B and X are as defined above; and

R² is hydrogen or a C₁₋₄ alkyl group;

A is -O- or $-NR^1-$,

K is selected from the group consisting of $-(CH_2)_pOC(O)-$, $-(CH_2)_pC(O)O-$,

 $-(CH_2)_pOC(O)O-$, $-(CH_2)_pNR^3-$, $-(CH_2)_pNR^3C(O)-$,

 $-(CH_2)_pC(O)NR^3-$, $-(CH_2)_pNR^3C(O)O-$, $-(CH_2)_pOC(O)NR^3-$,

-(CH₂)_pNR³C(O)NR³- (in which the groups R³ are the same or different), -(CH₂)_pO-,

-(CH₂)_pSO₃ -, and, optionally in combination with B, a valence bond

p is from 1 to 12; and

 R^3 is hydrogen or a C_1 - C_4 alkyl group.

55. (Withdrawn) A method according to claim 54 in which X is a group having the general formula IV:

where the groups R^{11} are the same or different and each is hydrogen or C_{1-4} alkyl, and m is from 1 to 4.

56. (Withdrawn) A method according to claim 54 in which the ethylenically unsaturated monomers include a surface binding monomer having the general formula II

$$Y^1R^4$$
 II

wherein Y^1 is selected from the group consisting of

$$H_2C = C - C - A^1 - C$$

 $CH_2=C(R^5)-CH_2-O-, CH_2=C(R^5)-CH_2 OC(O)-, CH_2=C(R^5)OC(O)-, CH_2=C(R^5)-O-, CH_2=C(R^5)CH_2OC(O)N(R^6)-, R^7OOCCR^5=CR^5C(O)-O-, R^5CH=CHC(O)O-, R^5CH=C(COOR^7)CH_2-C(O)-O-,$

wherein:

R⁵ is hydrogen or a C₁-C₄ alkyl group;

R⁶ is hydrogen or a C₁-C₄ alkyl group or R⁶ is R⁴;

R⁷ is hydrogen or a C₁₋₄ alkyl group;

 A^1 is -O- or -NR⁶-; and

 K^1 is selected from the group consisting of -(CH₂)_qOC(O)-, -(CH₂)_qC(O)O-,

 $-(CH_2)_qOC(O)O-$, $-(CH_2)_qNR^8-$, $-(CH_2)_qNR^8C(O)-$,

 $-(CH_2)_qC(O)NR^8-$, $-(CH_2)_qNR^8C(O)O-$, $-(CH_2)_qOC(O)NR^8-$,

-(CH₂)_qNR⁸C(O)NR⁸- (in which the groups R⁸ are the same or different), -(CH₂)_qO-,

-(CH₂)_qSO₃ -, and a valence bond

q is from 1 to 12;

and R^8 is hydrogen or a $C_1\text{-}C_4$ alkyl group;

and R⁴ is a surface binding group, selected from hydrophobic groups, ionic groups, reactive groups capable of forming covalent bonds with surface functional groups on the surface of the tube and crosslinkable groups capable of forming intermolecular crosslinks, optionally in conjunction with curing agents.

- 56. (Withdrawn) A method according to claim 52 in which the ethylenically unsaturated monomers comprise
 - a) a zwitterionic monomer of the general formula

in which

R is hydrogen or methyl;

B is C₂₋₆-alkanediyl; and

X is a group having the general formula IV:

where the groups R^{11} are the same or different and each is hydrogen or C_{1-4} alkyl, and m is from 1 to 4;

b) a surface binding monomer of the general formula

in which

R⁵ is hydrogen or methyl; and

R⁴ is selected from the group consisting of straight and branched alkyl, alkoxyalkyl and oligoalkoxyalkyl groups comprising 6 to 24 carbon atoms, unsubstituted or substituted by one or more fluorine atoms and optionally containing one or more carbon-carbon double or triple bonds; and

c) a silyl group containing monomer of the general formula

in which

R²³ is hydrogen or methyl;

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 R^{30} is a C_{2-24} alkanediyl group; and each R^{26} is methyl or ethyl.

- 58. (Withdrawn) A method according to claim 57 in which in the curing step c) the groups -Si(OR²⁶)₃ are reacted to cross-link the polymer.
- 59. (Withdrawn) A method according to claim 44 including, after step c), sterilising the coated assembly by contact with ethylene oxide.